**Template #87: Analytical methods *(Version [8.3]-[July 2023])***

The following table gives a detailed description of the type of information prompted for by the data entry fields.

| **Line no.** | **Field name** | **Field type****Display type** | **Picklist****Freetext template** | **Help text** | **Remarks** **Guidance** **Cross-reference** |
| --- | --- | --- | --- | --- | --- |
|  | **Administrative data** | **Header 1** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  |  |  |
|  | Endpoint | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- analysis of the microorganism as manufactured (QC)- analytical methods- analytical profile of batches- methods for post-approval control and monitoring purposes- methods for providing information on possible variability of seed stock/active micro-organism- methods for providing information on purity of seed stock/active micro-organism- methods for relevant impurities and/or metabolites of concern- methods for risk assessment- methods for the analysis of the (formulated) product- methods for the analysis of the active substance as manufactured (QC)- methods for the determination of residues- methods to determine storage stability/shelf life- methods to differentiate a mutant of the micro-organism from the parent wild strain- methods to identify and quantify contaminating microorganisms- methods used for monitoring purposes to determine and quantify residues (viable or non-viable)- methods, procedures and criteria used to establish the presence and identity of the microorganism, analysis of the microorganism as manufactured- other: | From the picklist select the relevant endpoint addressed by this study summary. In some cases there is only one endpoint title, which may be entered automatically depending on the software application.If multiple study types are covered by the same data entry form, the specific study type should be selected. If none matches, select the more generic endpoint description '<Generic endpoint>, other' (e.g. Skin irritation / corrosion, other) and give an explanation in the adjacent text field. The generic endpoint title reflects the title of the corresponding OECD Harmonised Template (OHT).Please note: For (Q)SAR studies, if an 'in silico' option does not exist, the generic endpoint title should be selected, normally with no need to fill in the adjacent text field, as '(Q)SAR' needs to be indicated in field 'Type of information' and the model should be described in field 'Justification of non-standard information' or 'Attached justification'. A specific endpoint title may be used, if addressed by the (Q)SAR information, i.e. the model behind has been validated by experimental data addressing this endpoint.Note: For the purpose of OHTs, an 'endpoint' is defined in the rather broad sense as an observable or measurable inherent property of a chemical substance which may be specified by the relevant regulatory framework as 'information requirement' (e.g. Boiling point, Sub-chronic toxicity: oral, Fish early-life stage toxicity). In a narrower sense, the term '(eco)toxicity endpoint' refers to an outcome or effect observed in a study. |  |
|  | Type of information | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- experimental study- experimental study planned- experimental study planned (based on read-across)- (Q)SAR- calculation (if not (Q)SAR)- read-across based on grouping of substances (category approach)- read-across from supporting substance (structural analogue or surrogate)- read-across from similar mixture/product- mixture rules calculation- weight of evidence justification/conclusion- not specified- other: | Select the appropriate type of information, e.g. ' experimental study', ' experimental study planned' or, if alternatives to testing apply, '(Q)SAR', 'read-across ...'. In the case of calculated data, the value 'calculation (if not (Q)SAR)' should only be chosen if the study report does not clearly indicate whether it is based on '(Q)SAR'.If the information is taken from a handbook or review article, select the relevant item, e.g. ‘experimental study’, if this is provided in the information source. Otherwise select ‘not specified’. Please note: In field ‘Reference type’ the option ‘review article or handbook’ should be selected. In general, the option 'not specified' should be selected if the submitter lacks the knowledge of the type of information. The option 'other:' can be used if another than a pre-defined item applies.In the case of read-across, follow the instructions related to the relevant legislation, for instance as to whether the (robust) study summary should be entered in a separate data set defined for the read-across (source) substance and referenced in the target substance dataset.If 'experimental study planned' or 'experimental study planned (based on read-across)' is indicated (in some legislations also defined as 'testing proposal' or 'undertaking of intended submission'), the submitter should include as much information as possible on the planned study in order to support the evaluation of the proposal. Typically, this would include at least the test guideline, information on the test material, the species and the route of administration in the corresponding distinct fields, as appropriate.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on whether specific fields should be completed and/or further details should be attached in field 'Attached background material'. |  |
|  | Adequacy of study | List (picklist)Display: Basic | **Picklist values:**- key study- supporting study- weight of evidence- disregarded due to major methodological deficiencies- other information | Indicate the adequacy of a (robust) study summary in terms of usefulness for hazard/risk assessment purposes depending on the relevant legislation.Note: This field is only applicable (or active) if neither 'waiving of standard information' nor 'experimental study planned' has been selected in field 'Type of information'.Explanation: - key study: In general, a key study is the study that has been identified as most suitable to describe an endpoint from the perspective of quality, completeness and representativity of data. - supporting study: Any other adequate study that is considered supportive for the key study or key studies. - weight of evidence: A record that contributes to a weight of evidence justification for the non-submission of a particular (adequate) study. The weight of evidence justification is normally endpoint-related, i.e. based on all available records included in the weight of evidence evaluation. A short reasoning for why a given record is used in this respect can be provided in field 'Detailed justification / remarks'. - disregarded due to major methodological deficiencies: study that demonstrates a higher concern than the key study/ies, but is not used as key study because of flaws in the methodology or documentation. This phrase should be selected for justifying why a potentially critical result has not been used for the hazard assessment. The lines of argumentation should be provided in field 'Rationale for reliability incl. deficiencies', accompanied by the appropriate reliability score.- other information: any other non-relevant information which does not need to be flagged specifically as 'disregarded due to major methodological deficiencies'.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. | **Guidance for field condition:**Condition: Field active only if 'Type of information' is not 'experimental study planned' and not ‘experimental study planned (based on read-across)’ and field 'Data waiving' is not populated (except for migrated data) |
|  | Robust study summary | Check boxDisplay: Basic |  | Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Robust Study Summary' or in combination with 'Adequacy of study'. Explanation: The term 'Robust Study Summary' is actually used only to describe the technical content of a very detailed summary of an experimental study or of any other relevant information. It is a priori no synonym with the term 'Key study', although a key study should usually be submitted in the form of Robust Study Summary. However, a Robust Summary may also be useful for other adequate studies that are considered supportive of the key study or even for inadequate studies if they can be used for a weight-of-evidence analysis. Also for studies that are flawed, but indicate critical results, Robust Study Summaries highlighting the weaknesses of the studies need to be elaborated. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Used for classification | Check boxDisplay: Basic |  | Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Used for classification'.Explanation: In some use cases it may be necessary to indicate those records that are used for the classification of that substance, e.g. according to UN GHS. If not relevant, disregard this field. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Used for SDS | Check boxDisplay: Basic |  | Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'SDS information'. Explanation: 'SDS' stands for Safety Data Sheet. In some use cases it may be necessary to indicate those records that are used for the compilation of SDS information. If not relevant, disregard this field. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Study period: start date | DateDisplay: Basic |  | If applicable indicate the period during which the study was conducted, i.e. start and end date. Note: independent of the study period, the in-life period (i.e. the phase of a study following treatment in which the test system is alive/growing) may have to be specified for some toxicology endpoints. |  |
|  | End date | DateDisplay: Basic |  |  |  |
|  | Remark | Text (255 char.)Display: Basic |  |  |  |
|  | Reliability | List (picklist)Display: Basic | **Picklist values:**- 1 (reliable without restriction)- 2 (reliable with restrictions)- 3 (not reliable)- 4 (not assignable)- other: | Enter an appropriate reliability score, according to Klimisch et al. (1997):1 = reliable without restrictions: “studies or data [...] generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline [...] or in which all parameters described are closely related/comparable to a guideline method.”2 = reliable with restrictions: “studies or data [...] (mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable.”3 = not reliable: “studies or data [...] in which there were interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (e.g. non-physiological pathways of application) or which were carried out or generated according to a method which is not acceptable, the documentation of which is not sufficient for assessment and which is not convincing for an expert judgment.”4 = not assignable: “studies or data [...] which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.).”The 'other:' option may be selected if a different scoring system is used. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.Note: This field is only applicable (or active) if neither 'waiving of standard information' nor 'experimental study planned' has been selected in field 'Type of information'.Note: The term reliability defines the inherent quality of a test report or publication relating to preferably standardised methodology and the way the method and results are described. More detailed criteria can be selected in field 'Justification'. |  |
|  | Rationale for reliability incl. deficiencies | List sup. (picklist with remarks - 32,000 char.)Display: Basic | **Picklist values:**- guideline study - [Reliability 1]- comparable to guideline study - [Reliability 1]- test procedure in accordance with national standard methods - [Reliability 1]- test procedure in accordance with generally accepted scientific standards and described in sufficient detail - [Reliability 1]- guideline study without detailed documentation - [Reliability 2]- guideline study with acceptable restrictions - [Reliability 2]- comparable to guideline study with acceptable restrictions - [Reliability 2]- test procedure in accordance with national standard methods with acceptable restrictions - [Reliability 2]- study well documented, meets generally accepted scientific principles, acceptable for assessment - [Reliability 2]- accepted calculation method - [Reliability 2]- data from handbook or collection of data - [Reliability 2]- significant methodological deficiencies - [Reliability 3]- unsuitable test system - [Reliability 3]- abstract - [Reliability 4]- secondary literature - [Reliability 4]- documentation insufficient for assessment - [Reliability 4]- results derived from a valid (Q)SAR model and falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 1 or 2]- results derived from a valid (Q)SAR model and falling into its applicability domain, with limited documentation / justification - [Reliability 2, 3 or 4]- results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 2 or 3]- results derived from a (Q)SAR model, with limited documentation / justification, but validity of model and reliability of prediction considered adequate based on a generally acknowledged source - [Reliability 2 or 3]- results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, and documentation / justification is limited - [Reliability 3 or 4]- results derived from a (Q)SAR model, with limited documentation / justification - [Reliability 4]- other: | Select an appropriate standard justification from the picklist, e.g. 'Comparable to guideline study with acceptable restrictions'. Additional explanations (e.g. deficiencies observed) can be entered in the related supplementary text field. Particularly if reliability scores 2 or 3 are assigned, indicate the concrete arguments for defending a study or relevant deficiencies.For QSAR results (i.e. 'Type of information' is '(Q)SAR') some pre-defined phrases are provided for indicating if the prediction results are considered reliable based on the scientifically validity of the (Q)SAR model used, its applicability to the query substance, and the adequacy of reporting. Please note: If (Q)SAR results are flagged as key study in field 'Adequacy of study', the relevance of the model used for the regulatory endpoint should be documented in the field where the (Q)SAR model is described, i.e. 'Justification for type of information', 'Attached justification' or 'Cross-reference'. | **Guidance for field condition:**Condition: Field active only if 'Type of information' is not 'experimental study planned' and not ‘experimental study planned (based on read-across)’.Condition 1: If 'Type of information' is not '(Q)SAR':- guideline study - [Reliability 1]- comparable to guideline study - [Reliability 1]- test procedure in accordance with national standard methods - [Reliability 1]- test procedure in accordance with generally accepted scientific standards and described in sufficient detail - [Reliability 1]- guideline study without detailed documentation - [Reliability 2]- guideline study with acceptable restrictions - [Reliability 2]- comparable to guideline study with acceptable restrictions - [Reliability 2]- test procedure in accordance with national standard methods with acceptable restrictions - [Reliability 2]- study well documented, meets generally accepted scientific principles, acceptable for assessment - [Reliability 2]- accepted calculation method - [Reliability 2]- data from handbook or collection of data - [Reliability 2]- significant methodological deficiencies - [Reliability 3]- unsuitable test system - [Reliability 3]- abstract - [Reliability 4]- secondary literature - [Reliability 4]- documentation insufficient for assessment - [Reliability 4]Condition 2: If 'Type of information' = '(Q)SAR':- results derived from a valid (Q)SAR model and falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 1 or 2]- results derived from a valid (Q)SAR model and falling into its applicability domain, with limited documentation / justification - [Reliability 2, 3 or 4]- results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 2 or 3]- results derived from a (Q)SAR model, with limited documentation / justification, but validity of model and reliability of prediction considered adequate based on a generally acknowledged source - [Reliability 2 or 3]- results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, and documentation / justification is limited - [Reliability 3 or 4]- results derived from a (Q)SAR model, with limited documentation / justification - [Reliability 4]- other: |
|  | Data waiving | List (picklist)Display: Basic | **Picklist values:**- study technically not feasible- study scientifically not necessary / other information available- exposure considerations- study waived due to provisions of other regulation- other justification | If appropriate, indicate here that the study has been waived, i.e. not performed. Select the basis from the picklist (e.g. 'study technically not feasible' or 'other justification'). Include a more detailed justification in the field 'Justification for data waiving' and, as needed, in field 'Justification for type of information', 'Attached justification' and/or 'Cross-reference'. Please note: the option 'study scientifically not necessary / other information available' covers cases where it can be justified that performance of a specific study prescribed by the relevant legislation is scientifically not necessary because reliable information is provided in other part(s) of the submission document.The option 'study waived due to provisions of other regulation' can be used for indicating that another, overlapping regulation allows or requires the waiving of a specific information requirement. This should then be detailed in the justification fields.If waiving is based on several lines of argumentation (e.g. ‘exposure considerations’ and ‘study scientifically not necessary / other information available’), create separate records for each.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use data waivers. | **Guidance for field condition:**Condition: Deactivate this field if any of the following fields is populated: 'Type of information', 'Adequacy of study', 'Reliability', 'Rationale for reliability'. |
|  | Justification for data waiving | List multi. (multi-select list with remarks - 32,000 char.)Display: Basic | **Picklist values:**- other: | In addition to the more generic justification selected in the preceding field 'Data waiving', it is highly recommended to provide a detailed justification. To this end you can either select one or multiple specific standard phrase(s) if it/they give an appropriate rationale of the description given in the preceding field 'Data waiving' or 'other:' and enter free text. Additional specific explanations should be provided if the pre-defined phrase(s) do no sufficiently describe the justification.More details can be provided using the following fields:- Text field adjacent to this field 'Justification for data waiving' (available after selecting any picklist item in this field);- Field 'Justification for type of information';- Field 'Attached justification';- Cross-reference (for referencing / linking to a justification or information referred to in the justification which is stored in another record, e.g. a record describing physico-chemical properties information used to support a data waiver)Please note: The pre-defined phrases are not necessarily exhaustive and may not always apply. Consult the guidance documents and waiving options in the relevant regulatory frameworks. If no suitable phrase is available from the picklist, enter a free text justification using the 'other:' option. | **Guidance for field condition:**Condition: Deactivate this field if any of the following fields is populated: 'Type of information', 'Adequacy of study', 'Reliability', 'Rationale for reliability'. |
|  | Justification for type of information | Text templateDisplay: Basic | **Freetext template:Option 1 Type 'Waiving of standard information'**JUSTIFICATION FOR DATA WAIVING[Specific explanation in addition to field 'Justification for data waiving']**Option 2 Type 'Experimental study planned / Testing proposal on vertebrate animals'**TESTING PROPOSAL ON VERTEBRATE ANIMALS[Please provide information for all of the points below. The information should be specific to the endpoint for which testing is proposed. Note that for testing proposals addressing testing on vertebrate animals under the REACH Regulation this document will be published on the ECHA website along with the third party consultation on the testing proposal(s).]NON-CONFIDENTIAL NAME OF SUBSTANCE:- Name of the substance on which testing is proposed to be carried out- Name of the substance for which the testing proposal will be used [if different from tested substance]CONSIDERATIONS THAT THE GENERAL ADAPTATION POSSIBILITIES OF ANNEX XI OF THE REACH REGULATION ARE NOT ADEQUATE TO GENERATE THE NECESSARY INFORMATION [please address all points below]:- Available GLP studies- Available non-GLP studies- Historical human/control data- (Q)SAR- In vitro methods- Weight of evidence- Grouping and read-across- Substance-tailored exposure driven testing [if applicable]- Approaches in addition to above [if applicable]- Other reasons [if applicable]CONSIDERATIONS THAT THE SPECIFIC ADAPTATION POSSIBILITIES OF ANNEXES VI TO X (AND COLUMN 2 THEREOF) OF THE REACH REGULATION ARE NOT ADEQUATE TO GENERATE THE NECESSARY INFORMATION:- [free text]FURTHER INFORMATION ON TESTING PROPOSAL IN ADDITION TO INFORMATION PROVIDED IN THE MATERIALS AND METHODS SECTION:- Details on study design / methodology proposed [if relevant]**Option 3 Type 'QSAR prediction'**1. SOFTWARE2. MODEL (incl. version number)3. SMILES OR OTHER IDENTIFIERS USED AS INPUT FOR THE MODEL4. SCIENTIFIC VALIDITY OF THE (Q)SAR MODEL[[Explain how the model fulfils the OECD principles for (Q)SAR model validation. Consider attaching the QMRF and/or QPRF or providing a link]- Defined endpoint:- Unambiguous algorithm:- Defined domain of applicability:- Appropriate measures of goodness-of-fit and robustness and predictivity:- Mechanistic interpretation:5. APPLICABILITY DOMAIN[Explain how the substance falls within the applicability domain of the model]- Descriptor domain:- Structural domain:- Mechanistic domain:- Similarity with analogues in the training set:- Other considerations (as appropriate):6. ADEQUACY OF THE RESULT[Explain how the prediction fits the purpose of classification and labelling and/or risk assessment]**Option 4 Type 'Read-across (analogue)'**REPORTING FORMAT FOR THE ANALOGUE APPROACH[Please provide information for all of the points below. Indicate if further information is included as attachment to the same record, or elsewhere in the dataset (insert links in 'Cross-reference' table)]1. HYPOTHESIS FOR THE ANALOGUE APPROACH[Describe why the read-across can be performed (e.g. common functional group(s), common precursor(s)/breakdown product(s) or common mechanism(s) of action]2. SOURCE AND TARGET CHEMICAL(S) (INCLUDING INFORMATION ON PURITY AND IMPURITIES)[Provide here, if relevant, additional information to that included in the Test material section of the source and target records]3. ANALOGUE APPROACH JUSTIFICATION[Summarise here based on available experimental data how these results verify that the read-across is justified]4. DATA MATRIX**Option 5 Type 'Read-across (category)'**REPORTING FORMAT FOR THE CATEGORY APPROACH[Please provide information for all of the points below addressing endpoint-specific elements that were not already covered by the overall category approach justification made available at the category level. Indicate if further information is included as attachment to the same record, or elsewhere in the dataset (insert links in 'Cross-reference' table)]1. HYPOTHESIS FOR THE CATEGORY APPROACH (ENDPOINT LEVEL)[Describe why the read-across can be performed]2. CATEGORY APPROACH JUSTIFICATION (ENDPOINT LEVEL[Summarise here based on available experimental data how these results verify that the read-across is justified]**Option 6 Type 'Weight of Evidence justification'**JUSTIFICATION FOR WEIGHT OF EVIDENCE- Relevance (including coverage) and reliability of each source of information compared with the study normally required for the information requirement.- Weighing of the sources of information (including overall coverage) to reach an overall conclusion for the information requirement.- Assessment of the uncertainty in the conclusion compared with the study normally required for the information requirement. | This field can be used for entering free text. As appropriate, one of the freetext templates can be selected (e.g. Justification for read-across (analogue)) to use pre-defined headers and bulleted elements. Delete/add elements as appropriate.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on what should be taken into account when providing justifications or whether specific reporting formats should be used.Explanations:Option 1: Type 'Waiving of standard information':This field should be used for entering any further lines of argumentation, if necessary, in addition to those provided in the field 'Justification for data waiving'.Option 2: Type 'Experimental study planned / Testing proposal':Further details can be entered here on the study design / methodology proposed in addition to details given in the distinct fields on test guideline, test material, species, route of administration and other relevant fields.Option 3: Type 'QSAR prediction':For describing a (Q)SAR model it is recommended to provide the QMRF as attachment instead of using the free text template.The QSAR Model Reporting Format (QMRF) is a harmonised template for summarising and reporting key information on QSAR models, including the results of any validation studies. The information is structured according to the OECD validation principles and can be compiled using the QMRF editor application.The JRC QSAR Model Database is intended to help to identify valid (Q)SARs (e.g. for the purpose of REACH). It provides information on the validity of QSAR models and can be browsed for published QMRFs.Based on this freetext template details on the QSAR model used can be given, in addition to the information provided in field 'Principles of method if other than guideline'.Please note: Any information that can be re-used for several study summaries can be entered once and then assigned to the relevant studies using either the 'Attached justification' or 'Cross-reference' feature.Option 4: Type 'Read-across (analogue)' and Option 5: Type 'Read-across (category)'This freetext template can be used and modified as appropriate for providing a justification for read-across, particularly if it is endpoint-specific.Please note: Any information that can be re-used for several study summaries can be entered once and then assigned to the relevant studies using either the 'Attached justification' or 'Cross-reference' feature. |  |
|  | **Attached justification** | **Block of fields (repeatable) Start** |  | The Attached justification feature can be used in case the justification is best provided in form of attached document(s).Copy this block of fields for attaching more than one file.Refer to the relevant legislation-specific guidance document as to the recommended use of the Attached justification feature. |  |
|  | Attached justification | Attachment (single)Display: Basic |  | Upload file by clicking the upload icon. |  |
|  | Reason / purpose | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- data waiving: supporting information- exposure-related information- read-across: supporting information- (Q)SAR model reporting (QMRF)- (Q)SAR prediction reporting (QPRF)- (Q)SAR model and prediction reporting (QMRF/QPRF)- (Q)SAR: supporting information- weight of evidence: supporting information- justification, other: | Indicate the reason for / purpose of the attached document. Select the relevant item from the picklist or, if none applies, select 'justification, other:' and specify. |  |
|  | **Attached justification** | **Block of fields (repeatable) End** |  |  |  |
|  | **Cross-reference** | **Block of fields (repeatable) Start** |  | The cross-reference feature can be used to refer to related information that is provided in another record of the dataset. This can be done either by entering just free text in the 'Remarks' field or by creating a link to the relevant record. The field 'Reason / purpose' allows for selecting a standard reason from the picklist and optionally to add free text explanation in the related supplementary text field.Refer to the relevant legislation-specific guidance document as to the recommended use of cross-references. |  |
|  | Reason / purpose for cross-reference | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- adverse outcome pathway (AOP)- assessment report- data waiving: supporting information- defined approach- exposure-related information- method used in study- read-across source- (Q)SAR model reporting (QMRF)- read-across: supporting information- reference to other assay used for intermediate effect derivation- reference to other study- reference to same study- weight of evidence source- other: | Select the appropriate reason of the cross-reference, i.e.- adverse outcome pathway (AOP) (in case the information is related to a key event that is part of an AOP). Consult the AOP wiki at: https://aopwiki.org) and provide the reference in the remarks field- assessment report (for referring to a record that contains an assessment report as attachment)- data waiving: supporting information (for referring to a record containing relevant endpoint information that is used to justify a data waiver)- defined approach for combining with results from another methods (in vitro, in chimico, in silico) - exposure-related information (for referring to a record containing exposure-related information that is used for instance to justify a data waiver)- read-across source (for linking to another study summary used for read-across. This can be useful in cases where results are derived from one or several read-across sources and recorded in a separate (target) study summary.)- read-across supporting information (for linking to another record which contains read-across justification that applies also for the current study summary)- (Q)SAR model reporting (QMRF) (for referring to a record containing the relevant model description. Note: The (Q)SAR prediction should be reported specifically for each endpoint in the field 'Justification for type of information'.)- reference to other assay used for intermediate effect derivation (for optional indication in a study summarising 'intermediate effects' if reference is made to the outcome of another assay)- reference to same study (e.g. if different species were tested and the results recorded in different records), - reference to other study (e.g. if another study is considered relevant in the interpretation of the test results), - other: (to be specified). |  |
|  | Related information | Link to endpoint (single)Display: Basic |  | As appropriate, select the record containing the related information, thus creating a link. | **Cross-reference:**AllSummariesAndRecords |
|  | Remarks | Text (32,768 char.)Display: Basic |  | This field can be used for including any remarks. |  |
|  | **Cross-reference** | **Block of fields (repeatable) End** |  |  |  |
|  | **Data source** | **Header 1** |  |  |  |
|  | Reference | Link to lit. reference (multiple)Display: Basic |  | Indicate the bibliographic reference of the study report or publication the study summary is based on. Provide general information such as Title, Author, Year, Bibliographic source, Testing Facility, Report Number, Study number, Report date etc., as requested in the core template for literature search (https://www.oecd.org/ehs/templates/Generic%20elements%20for%20all%20OHTs.zip). Always enter the primary reference in the first block of fields or sort it to the first position, if there are more than one reference to be cited. Copy this block of fields for specifying any other references related to this record (e.g. report of a preliminary study or other documentation). If results of a study report have been published, indicate the full citation of that publication(s) in addition to the reference of the original study. |  |
|  | Data access | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- data submitter is data owner- data submitter has Letter of Access- data no longer protected- data published- data submitter has permission to refer- not applicable- other: | Select appropriate indication for data access. Enter 'Not applicable' if the summary consists of information that is commonly accessible such as guidance on safe use.Select 'data submitter has permission to refer' if the information requirement can be covered based on a permission to refer to old data as issued by the relevant regulatory agency. In addition, provide, in the adjacent free-text field, the statement according to instructions you received from the relevant regulatory authority together with the permission to refer. |  |
|  | Data protection claimed | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes- yes, but willing to share- yes, but not willing to share | Indicate as appropriate. Note: 'yes' should be selected only if 'Data submitter is data owner' or 'Data submitter has Letter of Access'. Options 'yes, but willing to share' or 'yes, but not willing to share' may be relevant for specific regulatory programmes where the submitter is requested to indicate whether he is willing to share studies conducted (e.g. with vertebrates).In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. 'for justification see attached document X') |  |
|  | **Background** | **Header 1** |  |  |  |
|  | Background information | Text (2,000 char.)Display: Basic |  | Use this field to include any background information, if required, or any relevant introductory remarks on the study summary. Leave field empty if not applicable. Do not include information for which specific fields are provided. For instance, include any background information on the test substance in fields on 'Test materials'.PURPOSE OF THIS TEMPLATE:This template can be used for summarising analytical methods for determining a given substance in various matrices. Depending on the requirements of the relevant legislation, methods for the following matrices may have to be recorded: soil, sediment, suspended particulates, air, water (including drinking water), animal and human body fluids and tissues, plants, plant products, food and feedingstuffs, formulated product, other. |  |
|  | Method class | List multi. (multi-select list)Display: Basic | **Picklist values:**- primary- enforcement- Independent Laboratory Validation- confirmatory  | Indicate the method classes reported in this document. |  |
|  | **Materials and methods** | **Header 1** |  |  |  |
|  | **Test guideline** | **Block of fields (repeatable) Start** |  | Indicate according to which test guideline the study was conducted. If no test guideline was explicitly followed, but the methodology used is equivalent or similar to a specific guideline, you can indicate so in the 'Qualifier' subfield preceding the field 'Guideline'.Copy this block of fields for specifying more than one guideline (e.g. US EPA in addition to OECD guideline). |  |
|  | Qualifier | List (picklist)Display: Basic | **Picklist values:**- according to guideline- equivalent or similar to guideline- no guideline followed- no guideline available- no guideline required | Select appropriate qualifier, i.e.- 'according to guideline' (if a given test guideline was followed);- 'equivalent or similar to guideline' (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline);- 'no guideline followed' (if none of above qualifiers apply. If so, fill in field 'Principles of method if other than guideline');- 'no guideline available' (if so, fill in field 'Principles of method if other than guideline').- 'no guideline required' (if so, fill in field 'Principles of method if other than guideline'). |  |
|  | Guideline | List (picklist)Display: Basic | **Picklist values:**- OECD (2007) Guidance Document on Pesticide Residue Analytical Methods. ENV/JM/MONO (2007) 17- ASTM Method, other:- EPA methods- EPA Method 1311, Toxicity Characteristic Leaching Procedure (TCLP)- EPA Method 1312, Synthetic Precipitation Leaching Procedure- EPA Method 1614, Brominated diphenyl ethers in water, soil, sediment, and tissue by HRGC/HRMS- EPA Method 502.2, Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography with Photoionization and Electrolytic Conductivity Detectors in Series - Revision 2.1.- EPA Method 504.1, 1,2-Dibromoethane (EDB), 1,2-Dibromo-3-Chloropropane (DBCP), and 1,2,3- Trichloropropane (123TCP) in Water by Microextraction and Gas Chromatography - Revision 1.1.- EPA Method 505, Analysis of Organohalide Pesticides and Commercial Polychlorinated Biphenyl (PCB) Products in Water by Microextraction and Gas Chromatography - Revision 2.1.- EPA Method 506, Determination of Phthalate and Adipate Esters in Drinking Water by Liquid-Liquid Extraction or Liquid-Solid Extraction and Gas Chromatography with Photoionization Detection - Revision 1.1.- EPA Method 507, Determination of Nitrogen- and Phosphorus-Containing Pesticides in Water by Gas Chromatography with a Nitrogen-Phosphorus Detector - Revision 2.1.- EPA Method 508, Determination of Chlorinated Pesticides in Water by Gas Chromatography with an Electron Capture Detector - Revision 3.1.- EPA Method 508.1, Determination of Chlorinated Pesticides, Herbicides, and Organohalides by Liquid-Solid Extraction and Electron Capture Gas Chromatography -Revision 2.0.- EPA Method 508A, Screening for Polychlorinated Biphenyls by Perchlorination and Gas Chromatography - Revision 1.0.- EPA Method 515.1, Determination of Chlorinated Acids in Water by Gas Chromatography with an Electron Capture Detector - Revision 4.1.- EPA Method 515.2, Determination of Chlorinated Acids in Water using Liquid-Solid Extraction and Gas Chromatography with an Electron Capture Detector - Revision 1.1.- EPA Method 524.2, Measurement of Purgeable Organic Compounds in Water by Capillary Column Gas Chromatography/Mass Spectrometry - Revision 4.1.- EPA Method 525.1, Determination of Organic Compounds in Drinking Water by Liquids-Solid Extraction and Capillary Column Gas Chromatography/Mass Spectrometry, Revision 2.2.- EPA Method 525.2, Determination of Organic Compounds in Drinking Water by Liquid-Solid Extraction and Capillary Column Gas Chromatography/Mass Spectrometry -Revision 2.0.- EPA Method 531.1, Measurement of N-Methylcarbamoyloximes and N-Methylcarbamates in Water by Direct Aqueous Injection HPLC with Post Column Derivatization -Revision 3.1.- EPA Method 547, Determination of Glyphosate in Drinking Water by Direct-Aqueous-Injection b HPLC, Post-Column Derivatization, and Fluorescence Detection - July 1990.- EPA Method 548, Determination of Endothall in Drinking Water by Aqueous Derivatization, Liquid-Solid Extraction, and Gas Chromatography with Electron Capture Detection.- EPA Method 548.1, Determination of Endothall in Drinking Water by Ion Exchange Extraction, c Acidic Methanol Methylation and Gas Chromatography/Mass Spectrometry -Revision 1.0.- EPA Method 549.1, Determination of Diquat and Paraquat in Drinking Water by Liquid-Solid c Extraction and HPLC with Ultraviolet Detection - Revision 1.0.- EPA Method 550, Determination of Polycyclic Aromatic Hydrocarbons in Drinking Water By b Liquid-Liquid Extraction and HPLC with Coupled Ultraviolet and Fluorescence Detection.- EPA Method 550.1, Determination of Polycyclic Aromatic Hydrocarbons in Drinking Water by Liquid-Solid Extraction and HPLC with Coupled Ultraviolet and Fluorescence Detection.- EPA Method 551, Determination of Chlorination Disinfection Byproducts and Chlorinated Solvents in Drinking Water by Liquid-Liquid Extraction and Gas Chromatography with Electron Capture Detection.- EPA Method 551.1, Determination of Chlorination Disinfection Byproducts, Chlorinated Solvents, and Halogenated Pesticides/Herbicides in Drinking Water by Liquid-Liquid Extraction and Gas Chromatography with Electron-Capture Detection -Revision 1.0.- EPA Method 552, Determination of Haloacetic Acids in Drinking Water by Liquid-Liquid Extraction, Derivatization, and Gas Chromatography with Electron Capture Detection.- EPA Method 552.1, Determination of Haloacetic Acids and Dalapon in Drinking Water by Ion Exchange Liquid-Solid Extraction and Gas Chromatography with an Electron Capture Detector - Revision 1.0.- EPA Method 552.2, Determination of Haloacetic Acids and Dalapon in Drinking Water by Liquid-Liquid Extraction, Derivatization and Gas Chromatography with Electron Capture Detection - Revision 1.0.- EPA Method 553, Determination of Benzidines and Nitrogen-Containing Pesticides in Water by Liquid-Liquid Extraction or Liquid-Solid Extraction and Reverse Phase High Performance Liquid Chromatography/Particle Beam/Mass Spectrometry -Revision 1.1.- EPA Method 554, Determination of Carbonyl Compounds in Drinking Water by Dinitrophenylhydrazine Derivatization and High Performance Liquid Chromatography - Revision 1.0.- EPA Method 555, Determination of Chlorinated Acids in Water by High Performance Liquid Chromatography with a Photodiode Array Ultraviolet Detector - Revision 1.0.- EPA Method 601, Purgeable Hydrocarbons- EPA Method 602, Purgeable Aromatics- EPA Method 603, Acrolein and Acrylonitrile- EPA Method 604, Phenols- EPA Method 605, Benzidines- EPA Method 606, Phthalate Ester- EPA Method 607, Nitrosamines- EPA Method 608, Organochlorine Pesticides and PCBs- EPA Method 609, Nitroaromatics and Isophorone- EPA Method 610, Polynuclear Aromatic Hydrocarbons- EPA Method 611, Haloethers- EPA Method 612, Chlorinated Hydrocarbons- EPA Method 613, 2,3,7,8-Tetrachloro Dibenzo-p-Dioxin- EPA Method 624, Purgeables- EPA Method 625, Semivolatile Organic Compounds by Isotope Dilution GC/MS- EPA Method 8000B, Determinative Chromatographic Separations- EPA Method 8011, 1,2-Dibromoethane and 1,2-Dibromo-3-chloropropane by Microextraction and Gas Chromatography- EPA Method 8015B, Nonhalogenated Organics Using GC/FID- EPA Method 8021B, Aromatic and Halogenated Volatiles by Gas Chromatography Using Photoionization and/or Electrolytic Conductivity Detectors- EPA Method 8031, Acrylonitrile by Gas Chromatography- EPA Method 8032A, Acrylamide by Gas Chromatography- EPA Method 8033, Acetonitrile by Gas Chromatography with Nitrogen-Phosphorus Detection- EPA Method 8041, Phenols by Gas Chromatography- EPA Method 8061A, Phthalate Esters by Gas Chromatography with Electron Capture Detection (GC/ECD)- EPA Method 8070A, Nitrosamines by Gas Chromatography- EPA Method 8081A, Organochlorine Pesticides by Gas Chromatography- EPA Method 8082, Polychlorinated Biphenyls (PCBs) by Gas Chromatography- EPA Method 8091, Nitroaromatics and Cyclic Ketones by Gas Chromatography- EPA Method 8100, Polynuclear Aromatic Hydrocarbons- EPA Method 8111, Haloethers by Gas Chromatography- EPA Method 8121, Chlorinated Hydrocarbons by Gas Chromatography: Capillary Column Technique- EPA Method 8131, Aniline and Selected Derivatives by Gas Chromatography- EPA Method 8141A, Organophosphorus Compounds by Gas Chromatography: Capillary Column Technique- EPA Method 8151A, Chlorinated Herbicides by GC Using Methylation or Pentafluorobenzylation Derivatization- EPA Method 8260B, Volatile Organic Compounds by Gas Chromatography/Mass Spectrometry (GC/MS)- EPA Method 8270C, Semivolatile Organic Compounds by Gas Chromatography/Mass Spectrometry (GC/MS)- EPA Method 8275A, Semivolatile Organic Compounds (PAHs and PCBs) in Soils/Sludges and Solid Wastes Using Thermal Extraction/Gas Chromatography/Mass Spectrometry (TE/GC/MS)- EPA Method 8280A, The Analysis of Polychlorinated Dibenzo-p-Dioxins and Polychlorinated Dibenzofurans by High Resolution Gas Chromatography/Low Resolution Mass Spectrometry (HRGC/LRMS)- EPA Method 8290, Polychlorinated Dibenzodioxins (PCDDs) and Polychlorinated Dibenzofurans (PCDFs) by High-Resolution Gas Chromatography/High-Resolution Mass Spectrometry (HRGC/HRMS)- EPA Method 8310, Polynuclear Aromatic Hydrocarbons- EPA Method 8315A, Determination of Carbonyl Compounds by High Performance Liquid Chromatography (HPLC)- EPA Method 8316, Acrylamide, Acrylonitrile and Acrolein by High Performance Liquid Chromatography (HPLC)- EPA Method 8318, N-Methylcarbamates by High Performance Liquid Chromatography (HPLC)- EPA Method 8321A, Solvent Extractable Nonvolatile Compounds by High Performance Liquid Chromatography/Thermospray/Mass Spectrometry (HPLC/TS/MS) or Ultraviolet (UV) Detection- EPA Method 8325, Solvent Extractable Nonvolatile Compounds by High Performance Liquid Chromatography/Particle Beam/Mass Spectrometry (HPLC/PB/MS)- EPA Method 8330, Nitroaromatics and Nitramines by High Performance Liquid Chromatography (HPLC)- EPA Method 8331, Tetrazene by Reverse Phase High Performance Liquid Chromatography (HPLC)- EPA Method 8332, Nitroglycerine by High Performance Liquid Chromatography- EPA Method 8410, Gas Chromatography/Fourier Transform Infrared (GC/FT-IR) Spectrometry for Semivolatile Organics: Capillary Column- EPA Method 8430, Analysis of Bis(2-chloroethyl) Ether and Hydrolysis Products by Direct Aqueous Injection GC/FT-IR- EPA Method 8440, Total Recoverable Petroleum Hydrocarbons by Infrared Spectrophotometry- EPA Method, other:- EPA OPPTS 860.1340, Residue Analytical Method- EU methods- CEN 12393 (parts 1 and 2), multiresidue methods for the determination of pesticides residues by GC or LC-MS/MS- CEN 15662, modular QuEChERS for food of plant origin- EN 1233:1996 - Water quality - Determination of chromium - Atomic absorption spectrometric methods- EN 12918:1999 - Water quality - Determination of parathion, parathionmethyl and some other organophosphorus compounds in water by dichloromethane extraction and gas chromatographic analysis- EN 14207:2003 - Water quality - Determination of epichlorohydrin- EN 1622:2006 - Water quality - Determination of the threshold odour number (TON) and threshold flavour number (TFN)- EN 16618:2015 - Determination of acrylamide in food by liquid chromatography tandem mass spectrometry (LC-ESI-MS/MS)- EN 16691:2015 - Water quality - Determination of selected polycyclic aromatic hydrocarbons (PAH) in whole water samples - Method using solid phase extraction (SPE) with SPE-disks combined with gas chromatography mass spectrometry (GC-MS)- EN 16693:2015 - Water quality - Determination of organochlorine pesticides (OCP) in whole water samples - Method using solid phase extraction (SPE) with SPE-disks combined with gas chromatography mass spectrometry (GCMS)- EN 26777:1993 - Water quality - Determination of nitrite - Molecular absorption spectrometric method- EN 27888:1993 - Water quality - Determination of electrical conductivity- SANCO/825/00, Guidance document on pesticide residue analytical methods- SANCO/12116/2012, Working Document on Microbial Contaminant Limits for Microbial Pest Control Products- SANCO/3029/99, Residues: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414.- SANCO/3030/99, Technical Active Substance and Plant protection products: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex (Section 4) of Regulation (EU) No 283/2013 and Annex (Section 5) of Regulation (EU) No 284/2013.- SANTE 2017/10632 Rev. 3, Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods- SANTE 2017/10632 Rev. 4, Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods- SANTE/2020/12830 Rev.1, Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes- ISO standards- EN ISO 10304-1:2009 - Water quality - Determination of dissolved anions by liquid chromatography of ions - Part 1: Determination of bromide, chloride, fluoride, nitrate, nitrite, phosphate and sulfate- EN ISO 10304-4:1999 - Water quality - Determination of dissolved anions by liquid chromatography of ions - Part 4: Determination of chlorate, chloride and chlorite in water with low contamination- EN ISO 10523:2012 - Water quality - Determination of pH- EN ISO 11206:2013 - Water quality - Determination of dissolved bromate - Method using ion chromatography (IC) and post column reaction (PCR)- EN ISO 11732:2005 - Water quality - Determination of ammonium nitrogen - Method by flow analysis (CFA and FIA) and spectrometric detection- EN ISO 11885:2009 - Water quality - Determination of selected elements by inductively coupled plasma optical emission spectrometry (ICP-OES)- EN ISO 12020:2000 - Water quality - Determination of aluminium - Atomic absorption spectrometric methods- EN ISO 12846- EN ISO 12846:2012 - Water quality - Determination of mercury - Method using atomic absorption spectrometry (AAS) with and without enrichment- EN ISO 13395:1996 - Water quality - Determination of nitrite nitrogen and nitrate nitrogen and the sum of both by flow analysis (CFA and FIA) and spectrometric detection- EN ISO 14189:2016 - Water quality - Enumeration of Clostridium perfringens - Method using membrane filtration- EN ISO 14403-1:2012 - Water quality - Determination of total cyanide and free cyanide using flow analysis (FIA and CFA) - Part 1: Method using flow injection analysis (FIA)- EN ISO 14403-2:2012 - Water quality - Determination of total cyanide and free cyanide using flow analysis (FIA and CFA) - Part 2: Method using continuous flow analysis (CFA)- EN ISO 14911:1999 - Water quality - Determination of dissolved Li+, Na+, NH4+, K+, Mn2+, Ca2+, Mg2+, Sr2+ and Ba2+ using ion chromatography - Method for water and waste water- EN ISO 15061:2001 - Water quality - Determination of dissolved bromate - Method by liquid chromatography of ions- EN ISO 15586:2003 - Water quality - Determination of trace elements using atomic absorption spectrometry with graphite furnace- EN ISO 15682:2001 - Water quality - Determination of chloride by flow analysis (CFA and FIA) and photometric or potentiometric detection- EN ISO 15913:2003 - Water quality - Determination of selected phenoxyalkanoic herbicides, including bentazones and hydroxybenzonitriles by gas chromatography and mass spectrometry after solid phase extraction and derivatization- EN ISO 17294-2:2016 - Water quality - Application of inductively coupled plasma mass spectrometry (ICP-MS) - Part 2: Determination of selected elements including uranium isotopes- EN ISO 17852- EN ISO 17852:2008 - Water quality - Determination of mercury - Method using atomic fluorescence spectrometry- EN ISO 17993:2003 - Water quality - Determination of 15 polycyclic aromatic hydrocarbons (PAH) in water by HPLC with fluorescence detection after liquidliquid extraction- EN ISO 18412:2006 - Water quality - Determination of chromium(VI) - Photometric method for weakly contaminated water- EN ISO 18857-2:2011 - Water quality - Determination of selected alkylphenols - Part 2: Gas chromatographic-mass spectrometric determination of alkylphenols, their ethoxylates and bisphenol A in non-filtered samples following solid-phase extraction and derivatisation- EN ISO 23631- EN ISO 23631:2006 - Water quality - Determination of dalapon, trichloroacetic acid and selected haloacetic acids - Method using gas chromatography (GCECD and/or GC-MS detection) after liquid-liquid extraction and derivatization- EN ISO 23913:2009 - Water quality - Determination of chromium(VI) - Method using flow analysis (FIA and CFA) and spectrometric detection- EN ISO 5961:1995 - Water quality - Determination of cadmium by atomic absorption spectrometry (ISO 5961:1994)- EN ISO 6468:1996 - Water quality - Determination of certain organochlorine insecticides, polychlorinated biphenyls and chlorobenzenes - Gas chromatographic method after liquidliquid extraction- EN ISO 7887:2011 - Water quality - Examination and determination of colour- EN ISO 8467:1995 - Water quality - Determination of permanganate index- EN ISO 9963-1:1995 - Water quality - Determination of alkalinity - Part 1: Determination of total and composite alkalinity- ISO 17943:2016 - Water quality - Determination of volatile organic compounds in water. Method using headspace solid-phase micro-extraction (HS-SPME) followed by gas chromatography-mass spectrometry (GC-MS)- ISO 18862 - ISO 20179:2005 - Water quality - Determination of microcystins - Method using solid phase extraction (SPE) and high performance liquid chromatography (HPLC) with ultraviolet (UV) detection- ISO 21675:2019 - Water quality - Determination of perfluoroalkyl and polyfluoroalkyl substances (PFAS) in water - Method using solid phase extraction and liquid chromatographytandem mass spectrometry (LC-MS/MS)- other: | Select the applicable test guideline, e.g. 'OECD Guideline xxx'. If the test guideline used is not listed, choose 'other:' and specify the test guideline in the related text field. Information on the version and date of the guideline used and/or any other specifics can be entered in the next field 'Version / remarks'.If no test guideline can be specified, this should be indicated in the preceding field 'Qualifier'. The method used should then be shortly described in the field 'Principles of method if other than guideline', while details can be given in other distinct fields.Please note: Test guidelines used for the validation of (Q)SAR models should be reported in the description of the relevant model in field 'Justification for type of information' or 'Attached justification'. | **Guidance for field condition:**Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | Version / remarks | Text (2,000 char.)Display: Basic |  | In this text field, you can enter any remarks as applicable, particularly:- To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline);- To indicate if the study was performed prior to the adoption of the test guideline specified;- To indicate if the methodology used was based on an extension of the test guideline specified;- To indicate what protocol was followed for methods that allow the optional determination of more than one parameter if this cannot be indicated in a distinct field of the Materials and methods section. | **Guidance for field condition:**Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | Deviations | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes- no- not applicable- not specified | In case a test guideline or other standardised method was used, indicate if there are any deviations. Briefly state relevant deviations in the supplementary remarks field (e.g. 'other test system used', 'different exposure duration'); details should be described in the respective fields of the section MATERIALS AND METHODS. | **Guidance for field condition:**Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | **Test guideline** | **Block of fields (repeatable) End** |  |  |  |
|  | Principles of method if other than guideline | Text templateDisplay: Basic | **Freetext template:Option 1 Method of non-guideline study**- Principle of test:- Short description of test conditions:- Parameters analysed / observed:**Option 2 (Q)SAR**- Software tool(s) used including version:- Model(s) used:- Model description: see field 'Justification for non-standard information', 'Attached justification' and/or 'Cross-reference'- Justification of QSAR prediction: see field 'Justification for type of information', 'Attached justification' and/or 'Cross-reference' | If no guideline was followed, include a description of the principles of the test protocol or estimated method used in the study. As appropriate use either of the pre-defined freetext template options for 'Method of non-guideline study' or '(Q)SAR'. Delete / add elements and edit text set in square brackets [...] as appropriate.For a non-guideline experimental study a high-level freetext template can be used for summarising the principle of test, test conditions and parameters analysed / observed. If the freetext template for (Q)SAR is selected, indicate the QSAR model(s) or platform including version and the software tool(s) used. Detailed justification of the model and prediction should be provided in field(s) 'Justification for type of information', 'Attached justification' and/or 'Cross-reference' as appropriate.Details should be entered in appropriate distinct fields of section MATERIALS AND METHODS if available. Also provide a justification for using this method if appropriate. |  |
|  | GLP compliance | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes (incl. QA statement)- yes- no- not specified | Indicate whether the study was conducted following Good Laboratory Practice or not. In case 'yes’ is selected, a Quality Assurance (QA) statement must be provided with the report. You can give an explanation in the supplementary remarks field, e.g. for explaining why GLP was not complied with or for specifying which (national) GLP was followed. |  |
|  | Other quality assurance | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- ISO/IEC 17025 (General requirements for the competence of testing and calibration laboratories)- other: | Indicate any non-GLP quality assurance system adhered to, if any. |  |
|  | Matrix / medium | List multi. (multi-select list with remarks)Display: Basic | **Picklist values:**- active substance- air- animal and human body fluids and tissues- animal diet/feed- blood / serum- drinking water- eggs- fat- formulated product- ground water- honey- kidney- liver- meat- milk- plant, dry high sugar content matrices- plant, dry matrices- plant, high acid content- plant, high oil content- plant, high protein content- plant, high starch content- plant, high water content- sediment- soil- surface water- suspended particulates- test water / medium- urine- other: | Indicate the matrix for which the analytical method is described. In the supplementary remarks field, you can add explanations as appropriate.Note: The picklist is not descriptive as to whether analytical methods have to be submitted for each of the matrices provided in the picklist. Consult with the programme-specific guidance (e.g. EU BPD, OECD HPVC, Pesticides NAFTA or EU REACH) as to what matrices need to be addressed. If the methods for several matrices can be summarised in one record, you can copy this field for indicating the respective matrices. |  |
|  | **Test material** | **Header 2** |  |  |  |
|  | Test material information | Link to entity (single)Display: Basic |  | Select the appropriate Test Material Information (TMI) record. If not available in the repository, create a new one. You may also copy (clone) an existing TMI record, edit it and store it as new TMI.To change the link to an existing TMI, click the Delete button, then the Link button and proceed as described above.Depending on the purpose of the reporting or data submission, the information that must be provided may change. As a minimum, the chemical name, identifier and/or CAS number and molecular weight must be provided. | **Cross-reference:**TEST\_MATERIAL\_INFORMATION |
|  | Additional test material information | Link to entity (multiple)Display: Basic |  | Select additional Test material information record if relevant. For example, in longer terms studies more than one batch of test material can be needed or there may be differences between the labelled and unlabelled test materials. | **Cross-reference:**TEST\_MATERIAL\_INFORMATION |
|  | Specific details on test material used for the study | Text templateDisplay: Basic | **Freetext template:**SOURCE OF TEST MATERIAL- Source (i.e. manufacturer or supplier) and lot/batch number of test material:- Purity, including information on contaminants, isomers, etc.:RADIOLABELLING INFORMATION (if applicable)- Radiochemical purity:- Specific activity:- Locations of the label:- Expiration date of radiochemical substance:STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material:- Stability and homogeneity of the test material in the vehicle/solvent under test conditions (e.g. in the exposure medium) and during storage:- Stability in the medium, i.e. sensitivity of the test material to hydrolysis and/or photolysis:- Solubility and stability of the test material in the solvent/vehicle and the exposure medium:- Reactivity of the test material with the incubation material used (e.g. plastic ware):TREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding):- Preliminary purification step (if any):- Final concentration of a dissolved solid, stock liquid or gel:- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle):FORM AS APPLIED IN THE TEST (if different from that of starting material)- Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution:INFORMATION ON NANOMATERIALS- Chemical Composition:- Density:- Particle size & distribution:- Specific surface area:- Isoelectric point:- Dissolution (rate):TYPE OF BIOCIDE/PESTICIDE FORMULATION (if applicable)- Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application; formulated product seed treatment; solution in organic solvent seed treatment:OTHER SPECIFICS- Other relevant information needed for characterising the tested material, e.g. if radiolabelled, adjustment of pH, osmolality and precipitate in the culture medium to which the test chemical is added: | Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can include information on the pre-defined items, but not all or additional ones may be relevant.Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.If applicable, relevant available information on the following items should be given:SOURCE OF TEST MATERIAL- Source and lot/batch No. of test material- Expiration date of the lot/batch- Purity test date: provide if availableRADIOLABELLING INFORMATION- Radiochemical purity- Specific activity- Locations of the label- Expiration date of radiochemical substanceSTABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material- Stability under test conditions- Solubility and stability of the test substance in the solvent/vehicle- Reactivity of the test substance with the solvent/vehicle or the cell culture mediumTREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding)- Preliminary purification step- Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or dissolved solid) to final concentration and the solvent(s) used- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle)FORM AS APPLIED IN THE TEST (if different from that of starting material)Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution.FORMULATED PRODUCT (for biocides/pesticides)Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application: formulated product seed treatment; solution in organic solvent seed treatment.OTHER SPECIFICSProvide any other relevant information needed for characterising the tested material. |  |
|  | Specific details on test material used for the study (confidential) | Text templateDisplay: Basic (Confidential) | **Freetext template:**SOURCE OF TEST MATERIAL- Source (i.e. manufacturer or supplier) and lot/batch number of test material:- Purity, including information on contaminants, isomers, etc.:RADIOLABELLING INFORMATION (if applicable)- Radiochemical purity:- Specific activity:- Locations of the label:- Expiration date of radiochemical substance:STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material:- Stability and homogeneity of the test material in the vehicle/solvent under test conditions (e.g. in the exposure medium) and during storage:- Stability in the medium, i.e. sensitivity of the test material to hydrolysis and/or photolysis:- Solubility and stability of the test material in the solvent/vehicle and the exposure medium:- Reactivity of the test material with the incubation material used (e.g. plastic ware):TREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding):- Preliminary purification step (if any):- Final concentration of a dissolved solid, stock liquid or gel:- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle):FORM AS APPLIED IN THE TEST (if different from that of starting material)- Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution:INFORMATION ON NANOMATERIALS- Chemical Composition:- Density:- Particle size & distribution:- Specific surface area:- Isoelectric point:- Dissolution (rate):TYPE OF BIOCIDE/PESTICIDE FORMULATION (if applicable)- Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application; formulated product seed treatment; solution in organic solvent seed treatment:OTHER SPECIFICS- Other relevant information needed for characterising the tested material, e.g. if radiolabelled, adjustment of pH, osmolality and precipitate in the culture medium to which the test chemical is added: | Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can include information on the pre-defined items, but not all or additional ones may be relevant.Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.If applicable, relevant available information on the following items should be given:SOURCE OF TEST MATERIAL- Source and lot/batch No. of test material- Expiration date of the lot/batch- Purity test date: provide if availableRADIOLABELLING INFORMATION- Radiochemical purity- Specific activity- Locations of the label- Expiration date of radiochemical substanceSTABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material- Stability under test conditions- Solubility and stability of the test substance in the solvent/vehicle- Reactivity of the test substance with the solvent/vehicle or the cell culture mediumTREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding)- Preliminary purification step- Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or dissolved solid) to final concentration and the solvent(s) used- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle)FORM AS APPLIED IN THE TEST (if different from that of starting material)Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution.FORMULATED PRODUCT (for biocides/pesticides)Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application: formulated product seed treatment; solution in organic solvent seed treatment.OTHER SPECIFICSProvide any other relevant information needed for characterising the tested material. |  |
|  | **Analytical (primary) method** | **Header 2** |  |  |  |
|  | Instrument / detector | List multi. (multi-select list with remarks - 2,000 char.)Display: Basic | **Picklist values:**- EAAS- FAAS- GC-AFID- GC-ECD- GC-FID- GC-MS- GC-MS/MS- GC-PD- GC-PND / GC-NPD- HPLC-DAD- HPLC-UV- HPLC-UVPAD- IC- IC-SCD- ICP-MS- LC-MS- LC-MS/MS- LSC- Q-TOF-MS- SFC-MS/MS- UHPLC-DAD- UHPLC-MS- UHPLC-MS/MS- UHPLC-UV- atomic absorption spectroscopy - [AAS]- infrared spectroscopy - [IR]- nuclear magnetic resonance - [NMR]- screening procedures relevant to microorganisms:- other: | Indicate the instrument / detector used for the quantitative analysis of the parent compound / transformation products including the type of detector, e.g. 'HPLC-UV'. Multiple selection is possible if more than one method needs to be specified. Give any further details in field 'Details on analytical data collection method'.Note: If a residue analytical method is recorded, the instrument/detector used for the so-called data collection or data-gathering method should be specified here. Data collection method is the analytical method used to collect quantitative residue data by analysing the analyte(s) in the matrices. This method can be identical with or differ from the so-called enforcement method which has to be recorded under the heading 'Enforcement method (if applicable)'. Enforcement method is a validated analytical method which can be applied by the regulatory agency for enforcing the proposed tolerance, i.e. maximum residue limits (MRL) for pesticides. |  |
|  | Residue method | List sup. (picklist with remarks - 2,000 char.)Display: Basic | **Picklist values:**- common moiety- single analyte- multi analyte- other: | Indicate if the method detects multiple analytes. Further details can be provided in the remarks. |  |
|  | Extraction and clean-up | List sup. (picklist with remarks - 32,000 char.)Display: Basic | **Picklist values:**- QuEChERS Method- DFG-s19 - other: | Indicate the method used for extraction and clean-up. For major deviations or different methods, select other and provide remarks. |  |
|  | Flow diagram | Image uploadDisplay: Basic |  | Provide an image of the analytical method steps. |  |
|  | Further details on analytical method | Text templateDisplay: Detailed | **Freetext template:**COMPOUND (ANALYTE): ... - Method ID:  - Derivatisation (if any):  - Instrument/detector (if further details):  - Standardisation method:  - Stability of standard solution:  - Retention times:  - Other:   CHROMATOGRAMS: see Fig. attached  Standard Operating Procedure: see attachment  INTERFERING SUBSTANCE(S):   STABILITY OF PARENT AND TRANSFORMATION PRODUCTS AT VARIOUS STAGES OF ANALYSIS:   PROBLEMS / PRECAUTIONS  - Special problems encountered:  - Precautions to be taken during  - analysis of samples:  - handling of samples:  - storage of samples:   TOTAL TIME FOR COMPLETION: | Briefly describe further details on the principles of the method used to detect the analytes (to be specified, e.g. 'parent compound', 'parent and transformation products' or 'transformation product: .....') in matrices. Use freetext template and delete/add elements as appropriate. For example, add specific parameters in the case of inorganic chemicals. As an option you may include an excerpt from the study report.Attach relevant visual information (chromatograms, spectra) and standard operating procedure at the end of this summary.Note: If a residue analytical method is recorded, the details for the so-called data collection or data-gathering method should be specified here. As to the terms 'data collection method' and 'enforcement method' see help text for field 'Instrument / detector'.Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof. |  |
|  | **Enforcement method (if applicable)** | **Header 2** |  | This section should be completed if Enforcement has been selected in the Method Class field. Provide information only where it differs from the information provided in the ‘Principles of the analytical methods section’. |  |
|  | Instrument / detector for enforcement method | List multi. (multi-select list with remarks - 2,000 char.)Display: Basic | **Picklist values:**- EAAS- FAAS- GC-AFID- GC-ECD- GC-FID- GC-MS- GC-MS/MS- GC-PD- GC-PND / GC-NPD- HPLC-DAD- HPLC-UV- HPLC-UVPAD- IC- IC-SCD- ICP-MS- LC-MS- LC-MS/MS- LSC- Q-TOF-MS- SFC-MS/MS- UHPLC-DAD- UHPLC-MS- UHPLC-MS/MS- UHPLC-UV- atomic absorption spectroscopy - [AAS]- infrared spectroscopy - [IR]- nuclear magnetic resonance - [NMR]- screening procedures relevant to microorganisms:- other: | If no enforcement method is proposed or required, ignore this field. An enforcement method is a validated analytical method which can be applied by the regulatory agency for enforcing the proposed tolerance, i.e. maximum residue limits (MRL) for pesticides. If such a method is proposed indicate the instrument / detector used in the enforcement method.Multiple selection is possible if more than one method needs to be specified.Give any further details in field 'Details on data enforcement method'. |  |
|  | Residue method | List sup. (picklist with remarks - 2,000 char.)Display: Basic | **Picklist values:**- common moiety- single analyte- multi analyte- other: | Indicate if the method detects multiple analytes. Further details can be provided in the remarks. |  |
|  | Extraction and clean-up | List sup. (picklist with remarks - 32,000 char.)Display: Basic | **Picklist values:**- QuEChERS Method- DFG-s19 - other: | Indicate the method used for extraction and clean-up. For major deviations or different methods, select other and provide remarks. |  |
|  | Flow diagram | Image uploadDisplay: Basic |  | Provide an image of the analytical method steps. |  |
|  | Further details on enforcement method | Text templateDisplay: Detailed | **Freetext template:**COMPOUND (ANALYTE): ... - Method ID:  - Derivatisation (if any):  - Instrument/detector (if further details):  - Standardisation method:  - Stability of standard solution:  - Retention times:  - Other:   CHROMATOGRAMS: see Fig. attached  Standard Operating Procedure: see attachment  INTERFERING SUBSTANCE(S):   STABILITY OF PARENT AND TRANSFORMATION PRODUCTS AT VARIOUS STAGES OF ANALYSIS:   PROBLEMS / PRECAUTIONS  - Special problems encountered:  - Precautions to be taken during  - analysis of samples:  - handling of samples:  - storage of samples:   TOTAL TIME FOR COMPLETION: | 'Briefly describe further details on the principles of the method used to detect the analytes (to be specified, e.g. ''parent compound'', ''parent and transformation products'' or ''transformation product: .....'') in matrices. Use freetext template and delete/add elements as appropriate. For example, add specific parameters in the case of inorganic chemicals. As an option you may include an excerpt from the study report.Note: If a residue analytical method is recorded, the details for the so-called data collection or data-gathering method should be specified here. As to the terms ''data collection method'' and ''enforcement method'' see help text for field ''Instrument / detector''.Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof. |  |
|  | **Confirmatory method (if applicable)** | **Header 2** |  | This section should be completed if Confirmatory has been selected in the Method Class field. Provide information only where it differs from the information provided in the ‘Principles of the analytical methods section’. |  |
|  | Instrument / detector for confirmatory method | List multi. (multi-select list with remarks - 2,000 char.)Display: Basic | **Picklist values:**- EAAS- FAAS- GC-AFID- GC-ECD- GC-FID- GC-MS- GC-MS/MS- GC-PD- GC-PND / GC-NPD- HPLC-DAD- HPLC-UV- HPLC-UVPAD- IC- IC-SCD- ICP-MS- LC-MS- LC-MS/MS- LSC- Q-TOF-MS- SFC-MS/MS- UHPLC-DAD- UHPLC-MS- UHPLC-MS/MS- UHPLC-UV- atomic absorption spectroscopy - [AAS]- infrared spectroscopy - [IR]- nuclear magnetic resonance - [NMR]- screening procedures relevant to microorganisms:- other: | 'If not applicable, ignore this field. If a confirmatory method was used (i.e. applying techniques to demonstrate specificity in case the original method is not highly specific), indicate the instrument / detector used. Note: Not all picklist items may be relevant for a confirmatory technique.Multiple selection is possible if more than one method needs to be specified.Give any further details in field ''Details on data confirmatory method''.' |  |
|  | Residue method | List sup. (picklist with remarks - 2,000 char.)Display: Basic | **Picklist values:**- common moiety- single analyte- multi analyte- other: | Indicate if the method detects multiple analytes. Further details can be provided in the remarks. |  |
|  | Extraction and clean-up | List sup. (picklist with remarks - 32,000 char.)Display: Basic | **Picklist values:**- QuEChERS Method- DFG-s19 - other: | Indicate the method used for extraction and clean-up. For major deviations or different methods, select other and provide remarks. |  |
|  | Suitability of the method for confirmation | List multi. (multi-select list with remarks - 2,000 char.)Display: Basic | **Picklist values:**- simultaneous - In GC-MS, HPLC-MS: by monitoring at least 2 additional fragment ions (preferably m/z >100)- simultaneous - In GC-MS/MS, HPLC-MS/MS: by monitoring at least 1 additional SRM transition- simultaneous - High resolution MS: by monitoring 2 ions with a mass accuracy of ≤5 ppm (<1 mDa for m/z <200), preferably including the molecular ion, (de)protonated molecule or adduction and at least one fragment ion- chromatographic principle different from the original method- different stationary phase and/or mobile phase with significantly different selectivity- alternative detector- high resolution/accurate mass MS- in mass spectrometry an ionisation technique that leads to primary ions with different m/z ratio than the primary technique- other: | Indicate the method type used to confirm correct analyte identity and quantification. |  |
|  | Further details on confirmatory method | Text (2,000 char.)Display: Detailed |  | Briefly describe further details on the principles of the confirmatory method if any.Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof. |  |
|  | **Independent Laboratory Validation - ILV (if applicable)** | **Header 2** |  |  |  |
|  | Instrument / detector | List multi. (multi-select list with remarks - 2,000 char.)Display: Basic | **Picklist values:**- EAAS- FAAS- GC-AFID- GC-ECD- GC-FID- GC-MS- GC-MS/MS- GC-PD- GC-PND / GC-NPD- HPLC-DAD- HPLC-UV- HPLC-UVPAD- IC- IC-SCD- ICP-MS- LC-MS- LC-MS/MS- LSC- Q-TOF-MS- SFC-MS/MS- UHPLC-DAD- UHPLC-MS- UHPLC-MS/MS- UHPLC-UV- atomic absorption spectroscopy - [AAS]- infrared spectroscopy - [IR]- nuclear magnetic resonance - [NMR]- screening procedures relevant to microorganisms:- other: | Indicate the instrument / detector used for the quantitative analysis of the parent compound / transformation products including the type of detector, e.g. 'HPLC-UV'. Multiple selection is possible if more than one method needs to be specified. Give any further details in field 'Details on analytical data collection method'.Note: If a residue analytical method is recorded, the instrument/detector used for the so-called data collection or data-gathering method should be specified here. Data collection method is the analytical method used to collect quantitative residue data by analysing the analyte(s) in the matrices. This method can be identical with or differ from the so-called enforcement method which has to be recorded under the heading 'Enforcement method (if applicable)'. Enforcement method is a validated analytical method which can be applied by the regulatory agency for enforcing the proposed tolerance, i.e. maximum residue limits (MRL) for pesticides. |  |
|  | Residue method | List sup. (picklist with remarks - 2,000 char.)Display: Basic | **Picklist values:**- common moiety- single analyte- multi analyte- other: | Indicate if the method detects multiple analytes. Further details can be provided in the remarks. |  |
|  | Extraction and clean-up | List sup. (picklist with remarks - 32,000 char.)Display: Basic | **Picklist values:**- QuEChERS Method- DFG-s19 - other: | Indicate the method used for extraction and clean-up. For major deviations or different methods, select other and provide remarks. |  |
|  | Flow diagram | Image uploadDisplay: Basic |  | Provide an image of the analytical method steps. |  |
|  | Details on ILV | Text (32,768 char.)Display: Basic |  |  |  |
|  | **Any other information on materials and methods incl. tables** | **Header 2** |  |  |  |
|  |  | Text (rich-text area)Display: Basic |  | In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry. |  |
|  | **Results and discussion** | **Header 1** |  | Report the results for the method described in the ‘Principles of the analytical methods section’. |  |
|  | **Results using analytical (primary) method** | **Header 2** |  |  |  |
|  | **Recovery** | **Block of fields (repeatable) Start** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  | Set confidentiality and regulatory programme flags. |  |
|  | Analyte | Link to entity (single)Display: Basic |  | Link the reference substance of the analyte | **Cross-reference:**REFERENCE\_SUBSTANCE |
|  | Matrix | Text (255 char.)Display: Basic |  | Indicate the matrix the analyte was extracted from |  |
|  | MRM/ m/z | Numeric range (decimal)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca. | Report the mass transition monitored |  |
|  | Fortification level | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- mg/L- g/L- mg/kg- g/kg- other: |  |  |
|  | Number replicates | Numeric (integer)Display: Basic |  |  |  |
|  | Range recovery (%) | Numeric range (decimal)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca. |  |  |
|  | Mean recovery (%) | Numeric range (decimal)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca. |  |  |
|  | RSDr (%) | Numeric (decimal)Display: Basic |  | Relative standard deviation (RSD) of recovery |  |
|  | Remarks | Text (2,000 char.)Display: Basic |  |  |  |
|  | **Recovery** | **Block of fields (repeatable) End** |  |  |  |
|  | Additional details on recovery results | Text (32,768 char.)Display: Detailed |  |  |  |
|  | **Repeatability** | **Block of fields (repeatable) Start** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  | Set confidentiality and regulatory programme flags. |  |
|  | Analyte | Link to entity (single)Display: Basic |  | Link the reference substance of the analyte | **Cross-reference:**REFERENCE\_SUBSTANCE |
|  | Matrix | Text (255 char.)Display: Basic |  | Indicate the matrix the analyte was extracted from |  |
|  | Number replicates | Numeric (integer)Display: Basic |  |  |  |
|  | Mean content | Numeric (decimal)Display: Basic |  |  |  |
|  | RSD (%) | Numeric (decimal)Display: Basic |  |  |  |
|  | RSDr (%) | Numeric (decimal)Display: Basic |  |  |  |
|  | Horrat value | Numeric (decimal)Display: Basic |  |  |  |
|  | Remarks | Text (2,000 char.)Display: Basic |  |  |  |
|  | **Repeatability** | **Block of fields (repeatable) End** |  |  |  |
|  | **LOQ/LOD** | **Block of fields (repeatable) Start** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  | Set confidentiality and regulatory programme flags. |  |
|  | Analyte | Link to entity (single)Display: Basic |  | Link the reference substance of the analyte | **Cross-reference:**REFERENCE\_SUBSTANCE |
|  | Matrix | Text (2,000 char.)Display: Basic |  | Short description of the matrix tested e.g. ground water, maize whole plant |  |
|  | Limit of quantification | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- mg/L- g/L- mg/kg- g/kg- other: | Enter the Limit of quantification (LOQ) |  |
|  | Limit of detection | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- mg/L- g/L- mg/kg- g/kg- other: | Enter the Limit of detection (LOD) |  |
|  | Remarks | Text (2,000 char.)Display: Basic |  |  |  |
|  | **LOQ/LOD** | **Block of fields (repeatable) End** |  |  |  |
|  | **Calibration** | **Block of fields (repeatable) Start** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  | Set confidentiality and regulatory programme flags. |  |
|  | Analyte | Link to entity (single)Display: Basic |  |  | **Cross-reference:**REFERENCE\_SUBSTANCE |
|  | Standards | List multi. (multi-select list with remarks - 2,000 char.)Display: Basic | **Picklist values:**- matrix matched- internal- other: |  |  |
|  | Matrix | Text (255 char.)Display: Basic |  | Short description of the matrix tested e.g. ground water, maize whole plant |  |
|  | MRM/ m/z | Numeric range (decimal)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca. | Report the mass transition monitored |  |
|  | Calibration range | Numeric range (decimal with picklist)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca.**Picklist values:**- mg/L- g/L- mg/kg- g/kg- other: |  |  |
|  | Calibration equation | Text (2,000 char.)Display: Basic |  |  |  |
|  | Correlation coefficient (r) | Numeric (decimal)Display: Basic |  |  |  |
|  | Correlation coefficient (r2) | Numeric (decimal)Display: Basic |  |  |  |
|  | Number replicates | Numeric (integer)Display: Basic |  | Number of concentration levels/determinations (n) |  |
|  | Remarks | Text (2,000 char.)Display: Basic |  |  |  |
|  | **Calibration** | **Block of fields (repeatable) End** |  |  |  |
|  | Matrix effects (%) | Numeric (decimal)Display: Basic |  | Report the matrix effect (100 \* peak area or slope (matrix)/ peak area or slope (solvent) – 100) |  |
|  | Matrix effects remarks | Text (2,000 char.)Display: Basic |  | Provide additional information on the Matrix effects, further information should be provided if matrix effects exceed 20% |  |
|  | Additional details on analytical (primary) method | Text (32,768 char.)Display: Detailed |  |  |  |
|  | **Results using enforcement method (if applicable)** | **Header 2** |  |  |  |
|  | **Recovery** | **Block of fields (repeatable) Start** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  | Set confidentiality and regulatory programme flags. |  |
|  | Analyte | Link to entity (single)Display: Basic |  | Link the reference substance of the analyte | **Cross-reference:**REFERENCE\_SUBSTANCE |
|  | Matrix | Text (255 char.)Display: Basic |  | Indicate the matrix the analyte was extracted from |  |
|  | MRM/ m/z | Numeric range (decimal)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca. | Report the mass transition monitored |  |
|  | Fortification level | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- mg/L- g/L- mg/kg- g/kg- other: |  |  |
|  | Number replicates | Numeric (integer)Display: Basic |  |  |  |
|  | Range recovery (%) | Numeric range (decimal)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca. |  |  |
|  | Mean recovery (%) | Numeric range (decimal)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca. |  |  |
|  | RSDr (%) | Numeric (decimal)Display: Basic |  | Relative standard deviation (RSD) of recovery |  |
|  | Remarks | Text (2,000 char.)Display: Basic |  |  |  |
|  | **Recovery** | **Block of fields (repeatable) End** |  |  |  |
|  | Additional details on recovery results (enforcement method) | Text (32,768 char.)Display: Detailed |  |  |  |
|  | **Repeatability** | **Block of fields (repeatable) Start** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  | Set confidentiality and regulatory programme flags. |  |
|  | Analyte | Link to entity (single)Display: Basic |  | Link the reference substance of the analyte | **Cross-reference:**REFERENCE\_SUBSTANCE |
|  | Matrix | Text (255 char.)Display: Basic |  | Indicate the matrix the analyte was extracted from |  |
|  | Number replicates | Numeric (integer)Display: Basic |  |  |  |
|  | Mean content | Numeric (decimal)Display: Basic |  |  |  |
|  | RSD (%) | Numeric (decimal)Display: Basic |  |  |  |
|  | RSDr (%) | Numeric (decimal)Display: Basic |  |  |  |
|  | Horrat value | Numeric (decimal)Display: Basic |  |  |  |
|  | Remarks | Text (2,000 char.)Display: Basic |  |  |  |
|  | **Repeatability** | **Block of fields (repeatable) End** |  |  |  |
|  | **LOQ/LOD** | **Block of fields (repeatable) Start** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  | Set confidentiality and regulatory programme flags. |  |
|  | Analyte | Link to entity (single)Display: Basic |  | Link the reference substance of the analyte | **Cross-reference:**REFERENCE\_SUBSTANCE |
|  | Matrix | Text (2,000 char.)Display: Basic |  | Short description of the matrix tested e.g. ground water, maize whole plant |  |
|  | Limit of quantification | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- mg/L- g/L- mg/kg- g/kg- other: | Enter the Limit of quantification (LOQ) |  |
|  | Limit of detection | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- mg/L- g/L- mg/kg- g/kg- other: | Enter the Limit of detection (LOD) |  |
|  | Remarks | Text (2,000 char.)Display: Basic |  |  |  |
|  | **LOQ/LOD** | **Block of fields (repeatable) End** |  |  |  |
|  | **Calibration** | **Block of fields (repeatable) Start** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  | Set confidentiality and regulatory programme flags. |  |
|  | Analyte | Link to entity (single)Display: Basic |  |  | **Cross-reference:**REFERENCE\_SUBSTANCE |
|  | Standards | List multi. (multi-select list with remarks - 2,000 char.)Display: Basic | **Picklist values:**- matrix matched- internal- other: |  |  |
|  | Matrix | Text (255 char.)Display: Basic |  | Short description of the matrix tested e.g. ground water, maize whole plant |  |
|  | MRM/ m/z | Numeric range (decimal)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca. | Report the mass transition monitored |  |
|  | Calibration range | Numeric range (decimal with picklist)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca.**Picklist values:**- mg/L- g/L- mg/kg- g/kg- other: |  |  |
|  | Calibration equation | Text (2,000 char.)Display: Basic |  |  |  |
|  | Correlation coefficient (r) | Numeric (decimal)Display: Basic |  |  |  |
|  | Correlation coefficient (r2) | Numeric (decimal)Display: Basic |  |  |  |
|  | Number replicates | Numeric (integer)Display: Basic |  | Number of concentration levels/determinations (n) |  |
|  | Remarks | Text (2,000 char.)Display: Basic |  |  |  |
|  | **Calibration** | **Block of fields (repeatable) End** |  |  |  |
|  | Matrix effects (%) | Numeric (decimal)Display: Basic |  | Report the matrix effect (100 \* peak area or slope (matrix)/ peak area or slope (solvent) – 100) |  |
|  | Matrix effects remarks | Text (2,000 char.)Display: Basic |  | Provide additional information on the Matrix effects, further information should be provided if matrix effects exceed 20% |  |
|  | Additional details on enforcement method | Text (32,768 char.)Display: Detailed |  |  |  |
|  | **Results using confirmatory method (if applicable)** | **Header 2** |  |  |  |
|  | **Recovery** | **Block of fields (repeatable) Start** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  | Set confidentiality and regulatory programme flags. |  |
|  | Analyte | Link to entity (single)Display: Basic |  | Link the reference substance of the analyte | **Cross-reference:**REFERENCE\_SUBSTANCE |
|  | Matrix | Text (255 char.)Display: Basic |  | Indicate the matrix the analyte was extracted from |  |
|  | MRM/ m/z | Numeric range (decimal)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca. | Report the mass transition monitored |  |
|  | Fortification level | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- mg/L- g/L- mg/kg- g/kg- other: |  |  |
|  | Number replicates | Numeric (integer)Display: Basic |  |  |  |
|  | Range recovery (%) | Numeric range (decimal)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca. |  |  |
|  | Mean recovery (%) | Numeric range (decimal)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca. |  |  |
|  | RSDr (%) | Numeric (decimal)Display: Basic |  | Relative standard deviation (RSD) of recovery |  |
|  | Remarks | Text (2,000 char.)Display: Basic |  |  |  |
|  | **Recovery** | **Block of fields (repeatable) End** |  |  |  |
|  | **Repeatability** | **Block of fields (repeatable) Start** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  | Set confidentiality and regulatory programme flags. |  |
|  | Analyte | Link to entity (single)Display: Basic |  | Link the reference substance of the analyte | **Cross-reference:**REFERENCE\_SUBSTANCE |
|  | Matrix | Text (255 char.)Display: Basic |  | Indicate the matrix the analyte was extracted from |  |
|  | Number replicates | Numeric (integer)Display: Basic |  |  |  |
|  | Mean content | Numeric (decimal)Display: Basic |  |  |  |
|  | RSD (%) | Numeric (decimal)Display: Basic |  |  |  |
|  | RSDr (%) | Numeric (decimal)Display: Basic |  |  |  |
|  | Horrat value | Numeric (decimal)Display: Basic |  |  |  |
|  | Remarks | Text (2,000 char.)Display: Basic |  |  |  |
|  | **Repeatability** | **Block of fields (repeatable) End** |  |  |  |
|  | **LOQ/LOD** | **Block of fields (repeatable) Start** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  | Set confidentiality and regulatory programme flags. |  |
|  | Analyte | Link to entity (single)Display: Basic |  | Link the reference substance of the analyte | **Cross-reference:**REFERENCE\_SUBSTANCE |
|  | Matrix | Text (2,000 char.)Display: Basic |  | Short description of the matrix tested e.g. ground water, maize whole plant |  |
|  | Limit of quantification | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- mg/L- g/L- mg/kg- g/kg- other: | Enter the Limit of quantification (LOQ) |  |
|  | Limit of detection | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- mg/L- g/L- mg/kg- g/kg- other: | Enter the Limit of detection (LOD) |  |
|  | Remarks | Text (2,000 char.)Display: Basic |  |  |  |
|  | **LOQ/LOD** | **Block of fields (repeatable) End** |  |  |  |
|  | **Calibration** | **Block of fields (repeatable) Start** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  | Set confidentiality and regulatory programme flags. |  |
|  | Analyte | Link to entity (single)Display: Basic |  |  | **Cross-reference:**REFERENCE\_SUBSTANCE |
|  | Standards | List multi. (multi-select list with remarks - 2,000 char.)Display: Basic | **Picklist values:**- matrix matched- internal- other: |  |  |
|  | Matrix | Text (255 char.)Display: Basic |  | Short description of the matrix tested e.g. ground water, maize whole plant |  |
|  | MRM/ m/z | Numeric range (decimal)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca. | Report the mass transition monitored |  |
|  | Calibration range | Numeric range (decimal with picklist)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca.**Picklist values:**- mg/L- g/L- mg/kg- g/kg- other: |  |  |
|  | Calibration equation | Text (2,000 char.)Display: Basic |  |  |  |
|  | Correlation coefficient (r) | Numeric (decimal)Display: Basic |  |  |  |
|  | Correlation coefficient (r2) | Numeric (decimal)Display: Basic |  |  |  |
|  | Number replicates | Numeric (integer)Display: Basic |  | Number of concentration levels/determinations (n) |  |
|  | Remarks | Text (2,000 char.)Display: Basic |  |  |  |
|  | **Calibration** | **Block of fields (repeatable) End** |  |  |  |
|  | Matrix effects (%) | Numeric (decimal)Display: Basic |  | Report the matrix effect (100 \* peak area or slope (matrix)/ peak area or slope (solvent) – 100) |  |
|  | Matrix effects remarks | Text (2,000 char.)Display: Basic |  | Provide additional information on the Matrix effects, further information should be provided if matrix effects exceed 20% |  |
|  | Additional details on confirmatory method | Text (32,768 char.)Display: Basic |  |  |  |
|  | **Independent laboratory validation (if applicable)** | **Header 2** |  | If not applicable, ignore this section Report the results for the ILV study so that they can be compared with the result provided for the Enforcement study. |  |
|  | **Recovery** | **Block of fields (repeatable) Start** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  | Set confidentiality and regulatory programme flags. |  |
|  | Analyte | Link to entity (single)Display: Basic |  | Link the reference substance of the analyte | **Cross-reference:**REFERENCE\_SUBSTANCE |
|  | Matrix | Text (255 char.)Display: Basic |  | Indicate the matrix the analyte was extracted from |  |
|  | MRM/ m/z | Numeric range (decimal)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca. | Report the mass transition monitored |  |
|  | Fortification level | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- mg/L- g/L- mg/kg- g/kg- other: |  |  |
|  | Number replicates | Numeric (integer)Display: Basic |  |  |  |
|  | Range recovery (%) | Numeric range (decimal)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca. |  |  |
|  | Mean recovery (%) | Numeric range (decimal)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca. |  |  |
|  | RSDr (%) | Numeric (decimal)Display: Basic |  | Relative standard deviation (RSD) of recovery |  |
|  | Remarks | Text (2,000 char.)Display: Basic |  |  |  |
|  | **Recovery** | **Block of fields (repeatable) End** |  |  |  |
|  | **Repeatability** | **Block of fields (repeatable) Start** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  | Set confidentiality and regulatory programme flags. |  |
|  | Analyte | Link to entity (single)Display: Basic |  | Link the reference substance of the analyte | **Cross-reference:**REFERENCE\_SUBSTANCE |
|  | Matrix | Text (255 char.)Display: Basic |  | Indicate the matrix the analyte was extracted from |  |
|  | Number replicates | Numeric (integer)Display: Basic |  |  |  |
|  | Mean content | Numeric (decimal)Display: Basic |  |  |  |
|  | RSD (%) | Numeric (decimal)Display: Basic |  |  |  |
|  | RSDr (%) | Numeric (decimal)Display: Basic |  |  |  |
|  | Horrat value | Numeric (decimal)Display: Basic |  |  |  |
|  | Remarks | Text (2,000 char.)Display: Basic |  |  |  |
|  | **Repeatability** | **Block of fields (repeatable) End** |  |  |  |
|  | **LOQ/LOD** | **Block of fields (repeatable) Start** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  | Set confidentiality and regulatory programme flags. |  |
|  | Analyte | Link to entity (single)Display: Basic |  | Link the reference substance of the analyte | **Cross-reference:**REFERENCE\_SUBSTANCE |
|  | Matrix | Text (2,000 char.)Display: Basic |  | Short description of the matrix tested e.g. ground water, maize whole plant |  |
|  | Limit of quantification | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- mg/L- g/L- mg/kg- g/kg- other: | Enter the Limit of quantification (LOQ) |  |
|  | Limit of detection | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- mg/L- g/L- mg/kg- g/kg- other: | Enter the Limit of detection (LOD) |  |
|  | Remarks | Text (2,000 char.)Display: Basic |  |  |  |
|  | **LOQ/LOD** | **Block of fields (repeatable) End** |  |  |  |
|  | **Calibration** | **Block of fields (repeatable) Start** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  | Set confidentiality and regulatory programme flags. |  |
|  | Analyte | Link to entity (single)Display: Basic |  |  | **Cross-reference:**REFERENCE\_SUBSTANCE |
|  | Standards | List multi. (multi-select list with remarks - 2,000 char.)Display: Basic | **Picklist values:**- matrix matched- internal- other: |  |  |
|  | Matrix | Text (255 char.)Display: Basic |  | Short description of the matrix tested e.g. ground water, maize whole plant |  |
|  | MRM/ m/z | Numeric range (decimal)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca. | Report the mass transition monitored |  |
|  | Calibration range | Numeric range (decimal with picklist)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca.**Picklist values:**- mg/L- g/L- mg/kg- g/kg- other: |  |  |
|  | Calibration equation | Text (2,000 char.)Display: Basic |  |  |  |
|  | Correlation coefficient (r) | Numeric (decimal)Display: Basic |  |  |  |
|  | Correlation coefficient (r2) | Numeric (decimal)Display: Basic |  |  |  |
|  | Number replicates | Numeric (integer)Display: Basic |  | Number of concentration levels/determinations (n) |  |
|  | Remarks | Text (2,000 char.)Display: Basic |  |  |  |
|  | **Calibration** | **Block of fields (repeatable) End** |  |  |  |
|  | Matrix effects (%) | Numeric (decimal)Display: Basic |  | Report the matrix effect (100 \* peak area or slope (matrix)/ peak area or slope (solvent) – 100) |  |
|  | Matrix effects remarks | Text (2,000 char.)Display: Basic |  | Provide additional information on the Matrix effects, further information should be provided if matrix effects exceed 20% |  |
|  | Additional details on independent laboratory validation | List (picklist)Display: Detailed | **Picklist values:**- identical to primary method- similar to primary method with deviations- other: | Use this field to detail any differences between the primary method and the ILV method. If this is reported in a separate study the ILV study should be cross-referenced to this study. |  |
|  | Remarks | Text (32,768 char.)Display: Detailed |  |  |  |
|  | **Any other information on results incl. tables** | **Header 2** |  |  |  |
|  |  | Text (rich-text area)Display: Basic |  | In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format.Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry. |  |
|  | **Overall remarks, attachments** | **Header 1** |  |  |  |
|  | Overall remarks | Text (rich-text area)Display: Basic |  | In this field, you can enter any overall remarks or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry. |  |
|  | **Attachments** | **Block of fields (repeatable) Start** |  | Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula).Copy this block of fields for attaching more than one file. |  |
|  | Type | List (picklist)Display: Basic | **Picklist values:**- full study report- standard operating procedure- relevant visual information (e.g. chromatogram, calibration curve, spectra)- other: | Specify the type of attachment inserted, for example the 'full study report'. |  |
|  | Attached (confidential) document | Attachment (single)Display: Basic (Confidential) |  | An electronic copy of the full study report or other documents can be attached as Word, pdf or other file types. |  |
|  | Attached (sanitised) documents for publication | Attachment (single)Display: Basic |  | An electronic copy of a public (non-confidential) version of the full study report or other relevant documents can be attached. This attachment should be sanitised if needed. |  |
|  | Remarks | Text (255 char.)Display: Basic |  | As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory. |  |
|  | **Attachments** | **Block of fields (repeatable) End** |  |  |  |
|  | **Applicant's summary and conclusion** | **Header 1** |  |  |  |
|  | Validity criteria fulfilled | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes- no- not applicable- not specified | State whether validity criteria in the test guideline have been fulfilled or not. Use supplementary remarks field to state the criteria and supporting information.Clearly indicate if the criteria used are not consistent with those given by the test guideline. If so, give justification in field 'Rationale for reliability incl. deficiencies' as to why this study summary is considered reliable. |  |
|  | Conclusions | Text (32,768 char.)Display: Basic |  | Enter any conclusions if applicable in addition to the information given in fields 'Key results' and 'Interpretation of results' (if any). |  |
|  | Executive summary | Text (rich-text area)Display: Basic |  | If relevant for the respective regulatory programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, copy it from the corresponding document or upload it if provided as htm or html document.Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof. |  |